

DG Therm User Manual / Mode d'emploi

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3035615 04/2012

DG THERM

User Manual

GRIFOLS

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PLEASE READ THESE INSTRUCTIONS CAREFULLY BEFORE
STARTING TO USE THE **DG THERM** INCUBATOR

Information about matters relating to the equipment safety can be found in section 2 “SAFETY INFORMATION”.

The symbols used in this manual are as follows:

WARNING!

Indicates a hazardous situation for persons (including patients), which has protective devices or systems. Nonetheless, it is advisable to notify the SUPERVISOR or the OPERATOR.



CAUTION!

Indicates a hazardous situation that could result in material damages to the equipment or other property. This situation can be avoided by following these instructions or using other types of protection.



NOTE:

Used for clarifications or additional or emphasized information.



Definitions:

SUPERVISOR: Individual responsible for the use and maintenance of the equipment and for ensuring that operators are adequately trained. In some standards this position is referred as RESPONSIBLE BODY.

OPERATOR: Person operating equipment for its intended purpose. The OPERATOR should have received appropriate training for this purpose.

QUALIFIED TECHNICIAN: Person responsible for the installation, repair and special maintenance of the equipment who has received specific training for this purpose.

All restrictions referred to SUPERVISOR are valid for the OPERATOR.

Equipment design and specifications are subject to change without prior notification.

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1 INTRODUCTION

THIS EQUIPMENT IS INTENDED FOR *IN VITRO*
DIAGNOSTIC USE ONLY.

1.1 Intended Use

The *DG Therm* Incubator is a device specifically designed to incubate *DG Gel* Cards and/or test tubes at 37°C for immunohematology applications.

1.2 Principle of Operation

Incubation takes place by means of a dry heating bath at 37°C for a pre-established time of 15 minutes. The *DG Therm* incubator has two independent timers that enable carrying out two independent incubation batches.

1.3 Product Limitations

The *DG Therm* incubator is only prepared to carry out incubation of *DG Gel* Cards and/or test tubes as described in section 1.1 “Intended Use” and should not be used for any other type of tests different from which it was designed for.

1.4 Operator Training

The use of the *DG Therm* incubator does not require specific training beyond that established by the laboratory itself.



2 SAFETY INFORMATION

2.1 Read Before Use

- Use the equipment only for the principle of operation described in this User Manual.
- Unless specifically instructed to do so, do not drop or put anything into any opening in the equipment.
- Do not use the equipment if it is not working properly, or if it has suffered any damage. Examples of defects typically include:
 - Visible damage caused by dropping the equipment.
 - Visible damage caused by liquid spillage.
 - Visible damage caused by subjection to prolonged storage and under unfavorable conditions or by subjection to severe transport stresses.
 - Damage to the flexible power supply cord or its plug.
- Do not use the equipment in hazardous atmosphere, or with hazardous materials for which the equipment has not been designed.
- Do not use the equipment in the presence of inflammable gases or volatile products.
- Do not use accessories which are not supplied or recommended by the manufacturer.
- The equipment may only be disassembled by a QUALIFIED TECHNICIAN, either for internal cleaning and/or for repairing. Before disassembling, the equipment must be unplugged.
- Before using any cleaning or decontaminating method described in section 7 “Maintenance”, the equipment must be unplugged.

2.2 Warnings and Precautions

The following indications are directly related to the safety of the equipment. These warnings and safety precautions must be observed in order to avoid possible harm to personnel and the instrument and to avoid false test interpretations.

2.2.1 General Precautions Regarding Use

- Inappropriate use of this equipment can increase the risk of personal injury or damage to the equipment.

- This equipment works with substances that carry a chemical or biological risk. The established regulations for working in laboratories in relation to the use of suitable gloves or other personal protective means should be followed.
- All areas of the instrument must be considered potentially biohazardous and handled with the appropriate care as specified in the laboratory's Standard Operating Procedures (SOPs).
- This equipment must be used only by the SUPERVISOR, OPERATORS and QUALIFIED TECHNICIANS.

2.2.2 Electrical Safety Precautions

- To avoid risk of electric shock, this equipment should only be connected to a grounded power supply.
- In order to totally disconnect the instrument from the power supply, the instrument must be unplugged.
- In the event of any liquid spillage on to the equipment, it must be disconnected from the electrical supply, cleaned up and decontaminated. The instrument must be disassembled only by a QUALIFIED TECHNICIAN, and it must not be connected again until it has been fully inspected by the QUALIFIED TECHNICIAN.
- Electromagnetic compatibility and electrical safety tests have been performed using the cord supplied by the manufacturer.
- Using cables other than those specified may result in increased electromagnetic emissions and/or decreased immunity malfunctions or damage to the equipment.
- Basic safety precautions should always be taken, including those indicated in section 2.1 "Read Before Use". Furthermore, before installing the equipment, section 5.2 "Installation Requirements" must be read.

2.2.3 Precautions Associated with Technical Specifications

- It is recommended that the relative humidity of the room where the equipment is installed be not less than 30%. Although the equipment may function normally with relative humidity below 30%, in extremely dry environments electrostatic discharge may damage the equipment.

2.2.4 Precautions Associated with Using *DG Gel* Cards

- Handle the *DG Gel* Cards following the instructions for use of the respective gel cards.

2.2.5 Precautions Associated with Maintenance

- During cleaning and/or decontamination processes, protective gloves must be used.
- Before the cleaning and decontamination procedures, all samples and cards should be removed from inside the equipment.
- The cleaning processes of the equipment surfaces should be carried out with the equipment unplugged from the electric power supply.
- Any part of the equipment that could come into contact with blood, serum samples or any other biological liquid should be treated as potentially contaminant.
- Before using any cleaning or decontamination product different to those recommended by the manufacturer, the SUPERVISOR should verify with the manufacturer that the methods proposed will not damage the equipment.
- The sodium hypochlorite solution is corrosive, irritating for the skin and eyes and toxic if inhaled, absorbed or ingested.
- Do not leak cleaning solution into the equipment openings.
- Do not disassemble the equipment in any case. If there is liquid inside, the cleaning and decontamination operation should be carried out by a QUALIFIED TECHNICIAN. Call the nearest Technical Service.

2.2.6 Precautions Associated with Transport and Storage

- The equipment must be decontaminated before being transported and/or stored.
- Only the original packaging should be used for transporting the equipment.

2.2.7 Precautions Associated with Disposal of Equipment

- The instrument should only be disassembled by authorized specialists.

- When the instrument reaches the end of its useful life it must be disposed of as electronic waste, according to local, state and national regulations.
- Please note that contaminated medical devices must be disposed of as medical/biohazardous waste and cannot be included in used electronic equipment recycling programs. In addition, certain electronic products must be returned directly to the manufacturer. Contact your sales representative for return instructions.

2.2.8 Precautions Associated with Operating Procedures

- Do not use the *DG Therm* incubator if it does not work Properly or has been damaged.
- In order to avoid undesired over-incubation or under-incubation of the *DG Gel Cards*, strictly follow the procedures described in section 6 “Operating procedure”.
- Gel cards should be removed immediately after the desired incubation time.
- When the incubation has finished with the timer modified by the OPERATOR, the *DG Therm* incubator will again show the time of 15 minutes predefined by Diagnostic Grifols, S.A.

2.2.9 Precaution Associated with Warranty

- Repairs should be exclusively carried out by personnel authorised for this purpose and below the standards conditions.

2.3 Equipment Labelling

The *DG Therm* incubator has the following labels:

- (1) Packaging Label
- (2) Product Label
- (3) Biohazard Label

(1) Packaging Label

The packaging label of the *DG Therm* incubator is located on the upper right part of the front side of the box. The packaging label is shown in Figure 1 below:

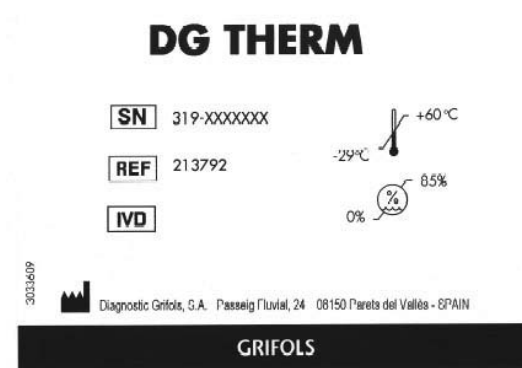


Figure 1: Packaging Label

The following symbols are used on the packaging labels:



Serial number



Catalog number



Temperature range permitted during storage and transport



Relative humidity range permitted during storage and transport



In vitro diagnostic medical device



Manufacturer

(2) Product Label

The product label is located on the rear part of the equipment containing technical information (voltage, frequency and power) as well as the model, serial number, manufacturing date, name and address of the manufacturer and regulatory information. The product label is as shown in Figure 2 below:



Figure 2: Product Label

Symbols additional to those described before are:



Date of manufacture



Safety mark that certifies that the instrument meets the applicable USA and Canadian safety standards.

(3) Biohazard Label

The biohazard label (Figure 3) is placed on the flap of the *DG Therm* Trays (No.5, Figure 4) and the thermal block (Figure 6). It warns the OPERATOR about potential biological risks caused by remaining substances deposited on the surfaces of the incubator and especially on the trays.



Figure 3: Biohazard Label

3 TECHNICAL SPECIFICATIONS

3.1 Technical Specifications

MODEL	DG THERM	
LOAD CAPACITY	<ul style="list-style-type: none"> • 24 DG Gel Cards • 24 sample tubes 	
INCUBATION BATCHES	2 batches with independent timer	
INCUBATION TEMPERATURE	37 °C ± 1°C	
TEMPERATURE UNITS	Programmable, °C or °F	
INCUBATION TIME	15 minutes, modifiable in steps of 5 minutes to 60 minutes	
PREHEATING TIME	Approximately 8 minutes	
ALARM SYSTEMS	Yes, two independent sensors to measure and control temperature	
ACOUSTIC ALARM	Yes, to indicate end of incubation and error situations	
VOLUME OF ACOUSTIC ALARM	Programmable, 3 levels	
INTERFACE	LCD screen and Buttons	
SUPPLY	Voltage:	100–240 V ~
	Frequency:	50-60 Hz
	Input power:	270 W
PROTECTION AGAINST ELECTRIC SHOCK	Class:	I
INSTALLATION CATEGORY	Overvoltage category II (local level, appliances, portal equipment, etc.)	

DIMENSIONS	325 mm (depth) x 295 mm (width) x 95 mm (height) or 13 in. (depth) x 12 in. (width) x 4 in. (height)	
WEIGHT	Approximately 4 kg. or 9 lbs	
OPERATING CONDITIONS:	Indoor use	
	Temperature:	15 °C to 30°C
	Maximum relative humidity non condensing:	80 %
	Maximum altitude:	3,000 m or 9,843 ft.
	Mains supply maximum voltage fluctuations:	±10% of nominal voltage
TRANSPORT AND STORAGE CONDITIONS	Temperature:	-29 °C to + 60 °C
	Maximum relative humidity non condensing:	85 %
PROTECTION AGAINST OVERHEATING	50 °C ± 5 °C	
USEFUL LIFE	5 years considering normal function of 8 hours/day and 200 days/year.	

3.2 Accessories

CODE	DESCRIPTION	PRESENTATION
213732	DG Therm Trays	6
230881	PT100 temperature probe for DG Gel Cards.	1
230879	Digital thermometer for PT100 probes	1

4 DESCRIPTION OF DG THERM

4.1 General Description of DG Therm Incubator

Figure 4 and Figure 5 below show the front and the rear views of the DG Therm incubator.

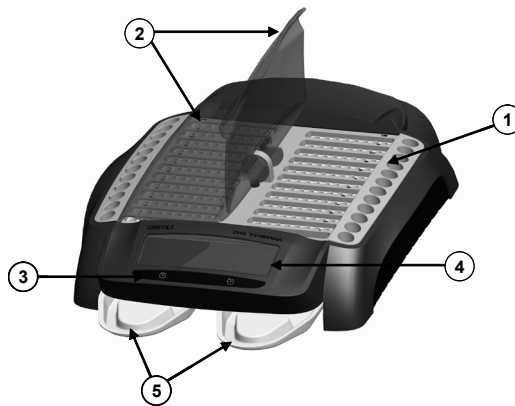


Figure 4: Front View of DG Therm Incubator

- (1) Thermal Block
- (2) Protective Covers
- (3) Start/Stop Timer Buttons **P1** and **P2**
- (4) Display
- (5) DG Therm Trays

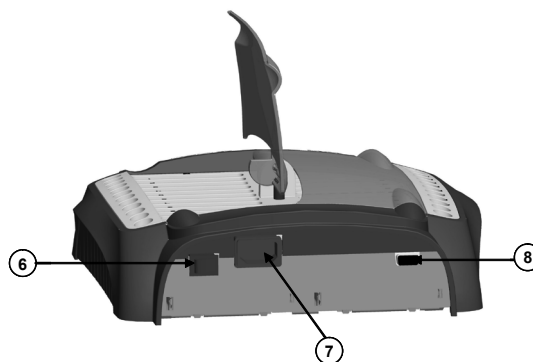


Figure 5: Rear View of the DG Therm Incubator

- (6) Power Switch
- (7) Power Cord Connection
- (8) Connection to a computer (for the exclusive use of the authorized Technical Service)

4.1.1 Thermal Block

The Thermal block shown in No.1 of Figure 6 is the area of the incubator designed to place *DG Gel Cards* and sample tubes for their heating at 37°C for the pre-established time.

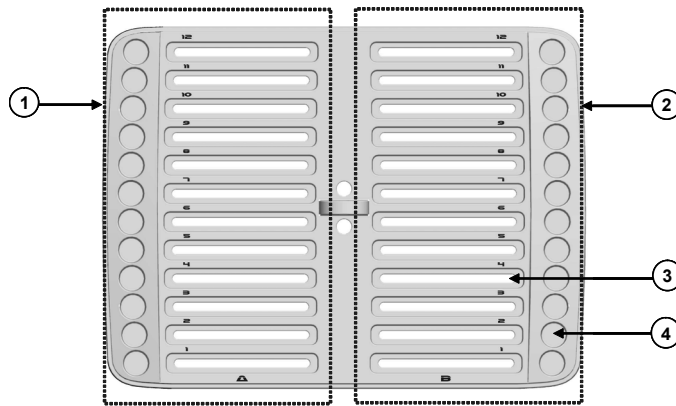




Figure 6: Thermal Block

- (1) Incubation area 
- (2) Incubation area 
- (3) Positions for *DG Gel Cards*
- (4) Positions for sample tubes

As shown in Figure 6, the Thermal block is divided into two Incubation areas (Nos. 1 and 2). Each one has a capacity of 12 *DG Gel cards* (No. 3) and 12 sample tubes that are aligned with the cards (No. 4).

4.1.2 Protective Cover

The *DG Therm* incubator has two coverings that fold laterally (No. 2, Figure 4). When closed, they keep the cards down to assure an optimum incubation of the *DG Gel Cards*.

4.1.3 Start/Stop Timer Buttons









The *DG Therm* incubator has two Start/Stop Buttons as shown in No. 3 of Figure 4, button **P**  (No.1, Figure 7) and button **P**  (No. 2, Figure 7), that allow starting and stopping independently for the two incubator timers.



Figure 7: **P**  and **P**  Buttons

- (1) **P** : Start/stop timer button 
- (2) **P** : Start/stop timer button 

4.1.4 Display

The Display (No. 4, Figure 8) informs the OPERATOR of the remaining time of incubation (controlled by Timers 1 and 2) and the temperature of the Thermal block. It also informs of possible error situations.

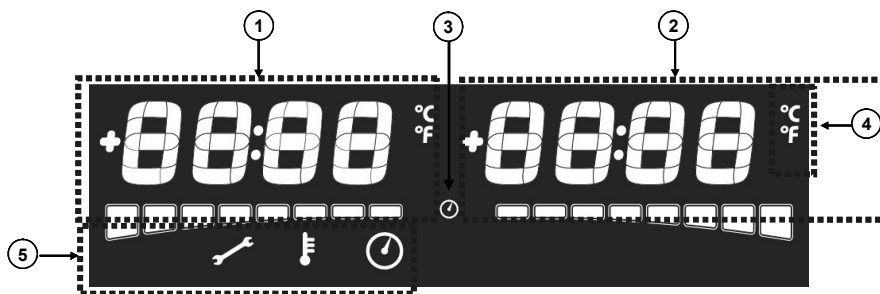


Figure 8: Display

- (1) Timer **1** information
- (2) Timer **2** information
- (3) Timer measurement indicator
- (4) Temperature units
- (5) Warnings area

4.1.4.1 Timers **1** and **2** Information

The DG Therm incubator has two independent Timers (No.1 and 2, Figure 9).

NOTE:







Although the equipment does not establish any predetermined correspondence between each Incubation area (**A** or **B**) and each Timer (**1** or **2**), due to its design, it is recommended using Timer **1** for incubations carried out in Incubation area **A** and Timer **2** for incubations carried out in Incubation area **B**.

In normal mode, the display shows, for each timer by means of a digital number and a progress bar (No. 3, Figure 9), the remaining incubation time. The progress bar is filled in as the pre-programmed time elapses.

Once incubation has finished, and if the timer is not stopped, the display will show flicker information on the time exceeded with respect to the pre-programmed time by means of the symbol **+** (No. 5, Figure 10).



Figure 9: Display with Batches in Execution

- (1) Timer  information
- (2) Timer  information
- (3) Timer  progress bar
- (4) Timer  progress bar

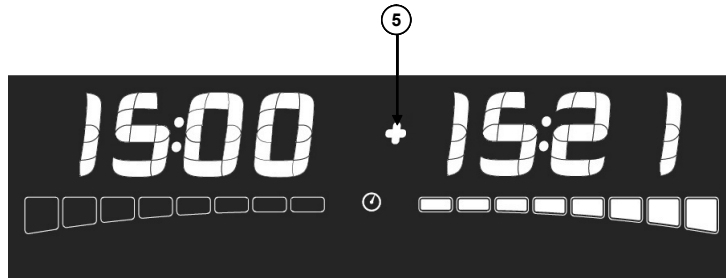


Figure 10: Display with Measurement of Time Exceeded in Timer 

- (5) Indication of time exceeded

4.1.4.2 Units

The *DG Therm* incubator enables informing the OPERATOR of the incubation temperature in °C or in °F. To change the option that appears on the screen, consult section “5.5 Configuration of Equipment”.

4.1.4.3 Warnings Area

This is located on the left lower part of the Display (No. 5 Figure 8) and informs, by means of symbols, of alarm situations during initialisation or incubation batch. These symbols are described below. For more information, consult section 12.1.





Contact the authorised Technical Service



Temperature out of range



Batch completed with Erroneous incubation time (Timer  or/and )

4.1.5 DG Therm Trays

DG Therm Trays (No. 5, Figure 4) are disposable and are located in the lower part of the incubator. They are used to collect any remains of samples or any other substance from accidental spillage during the use of the equipment.

The Trays also form part of the card elevation system of the thermal block.

5 INSTALLATION

5.1 Action upon Delivery

This equipment may be installed directly by the OPERATOR or SUPERVISOR.

5.2 Installation Requirements

The requirements for the place where the equipment is to be installed are as follows:

- If the equipment has been stored in other environmental conditions different from work conditions, it should be kept for at least one hour under work condition environment before being plugged in.
- For environmental conditions: See section 3.1 “Technical Specifications”.
- Space requirements: It is recommended to have a solid horizontal area of 400 mm in width and 550 mm in depth (includes space for connection to power supply).
- Do not place the equipment outdoors.
- Do not place the equipment where it could get wet.
- Do not place the equipment on a surface of flammable material.
- Do not position the equipment so that it is difficult to operate the mains switch. (No.6, Figure 5).
- Do not let the equipment or its flexible cord come into contact with surfaces which are too hot to touch.
- Do not place anything on top of the equipment.
- The electrical installation to which the equipment will be connected should comply with the necessary requirements of power supply, consumption and regulations (including protective earth).
- The plug should have a protective earth.
- Appliance coupler or plug shall be readily and easy accessible.

**WARNING!**

To completely disconnect the apparatus from mains remove the mains plug from the socket outlet or the appliance coupler.

5.3 Unpacking the Equipment

Once the appropriate place is selected for installation, unpack equipment according to the following instructions:

- Open the upper part of the box.
- Remove all protections and accessories.
- Remove the protection bag and place the equipment in the chosen position.
- Check that the equipment is not damaged due to the storage and transport.
- Check that all elements specified in the attached *Packing list* are included.

5.4 Installation Procedure

To install the *DG Therm* incubator, proceed as follows:

- Verify that the *DG Therm* Trays are completely inserted into the incubator and correctly placed.
- Verify that the Protective Covers open correctly.
- Verify the card elevator system as described in section 8.4 “Procedure for Qualification of Card Elevator System”.
- Connect the mains cord to the incubator (No.7, Figure 5) and the mains.
- Switch on the Main switch (No.6, Figure 5).
- Verify that the Display switches on and goes into preheating phase showing the symbols “--:--”.
- Once the preheating time has finished, verify that the Display shows for the timer 1 and 2, the pre-programmed time of 15 minutes.

The *DG Therm* incubator is supplied with a conformity certificate stating that the temperature of the thermal block (37°C) has been verified using instruments

calibrated by accredited entities. The *DG Therm* incubator does not need to be readjusted during its useful life if it is used under normal working conditions.

5.5 Configuration of Equipment

The *DG Therm* incubator has some pre-defined parameters that may be modified by the OPERATOR. Pre-defined values are the following:

- Acoustic signal volume: High
- Temperature units: °C
- Date and time: GMT tim zone

NOTE:

The Date and Time parameters are used to maintain traceability in a “log file” with relevant information and possible incidences that have occurred during the incubation phase. Accessibility to this file and its use are for the exclusive use of the authorized Technical Service.



To modify these parameters access the **Configuration Mode** as described below:

With the equipment switched off, keep the button **P** pressed down and turn on the Main switch (No.6, Figure 5). The *DG Therm* incubator is initialized in **Configuration Mode** and enables personalizing the parameters described:

- In **Configuration Mode** the Display will show the configuration menu for the selection of the acoustic signal volume.

The numeration shown corresponds to the following volumes:

- VOL 0: Deactivated
- VOL 1: Medium level volume
- VOL 2: High volume
- Press **P** to modify the value to the required level.
- Once the required level has been selected, press **P** to move onto the next parameter.

- The Display will automatically show the following configuration menu: Selection of temperature units.
- To change the units, press **P1** and select the desired units: °C or °F.
 - SEL °C: Temperature in degrees centigrade
 - SEL °F: Temperature in degrees Fahrenheit
- Once the level required has been selected, press **P1** to move onto the next parameter. Automatically, the Display will show flickering digits corresponding to the Date (YYYY.MM.DD) and the Time (HH:MM). Press **P2** to modify the value of each field and **P1** to move onto the next field. The date and time of the incubator are pre-programmed with respect to the GMT system and therefore should not be modified.
- Once the date and time has been introduced, save the configuration by keeping **P1** pressed down. The equipment will emit a long and continuous acoustic signal indicating that the configuration has been successfully saved.

The *DG Therm* incubator will automatically show the pre-programmed incubation time in the Display.



NOTE:

If no button is pressed for 15 seconds, changes are not recorded in the **Configuration Mode**.



NOTE:

To save the modification of any parameter (volume, units, date and time) it is necessary to keep **P1** or **P2** pressed down until the indicator emits the long and continuous acoustic signal. Otherwise, the OPERATOR will leave the **Configuration Mode** without recording the changes made.

6 OPERATING PROCEDURE

CAUTION!

Do not use the *DG Therm* incubator if it does not work correctly or has been damaged.




CAUTION!


To handle *DG Gel Cards* follow the instructions for use of the gel cards.



6.1 Execution of Incubation Batch

To properly use the *DG Therm* incubator, the following instructions should be followed:

- Activate the Main switch (No.6, Figure 5) and verify that the Display (No.4, Figure 4) is switched on. The incubator enters into a preheating phase in which the timer show the symbols “--:--” and the indicator of Temperature out of range () is flashing.

Once the work temperature is reached, the indicator  will be inactivated, a short sound will be emitted and the timers 1 and 2 will show the predefined incubation time.

NOTE:

During the preheating phase, the *DG Therm* incubator does not enable activating the timers. Do not introduce the cards into the Thermal block until the incubator has reached the incubation temperature and the timers show the pre-programmed incubation time.



- Open the cover of incubation area A and/or B where you wish to carry out the incubation batch.

- Place the *DG Gel* Cards into the slots of the Thermal Block (No.3, Figure 6) and if required the corresponding sample tubes in the positions aligned with the cards (No.4, Figure 6). With the cover open, the *DG Gel* Cards will remain lifted up with respect to the Thermal Block, thereby facilitating their positioning.
- Lower the cover of the incubator. The cards will be introduced into the Thermal Block so as to enable better heating.
- Press **P1** or **P2** to activate the timer that will indicate the incubation time of the batch of cards introduced.
- During incubation, the *DG Therm* incubator will show by means of the Display the remaining incubation time in minutes and seconds and will gradually complete the different elements that comprise the progress bar.
- Once incubation has finished, the acoustic indicator will be activated to indicate to the OPERATOR that the pre-established incubation time has finished and the Display will start to flash.

CAUTION!




Times showed by the timer of the *DG Therm* incubator (incubation time and time exceeded) are correct if the operator has worked as described in this section, in other words without delays due to deviation from the procedure.

CAUTION!



Before pressing the button to stop timer **P1** or **P2**, check which one has finished timing. To do this, see which display area shows the flickering time.

- Press **P1** or **P2** again to stop the corresponding timer. Once the incubation has finished, and if the timer is not stopped, the time that has exceeded the pre-established one and the sign  will flicker on the Display and the Acoustic alarm will be activated.

CAUTION!

Before pressing the button to stop timer **P1** or **P2**, check which one has finished timing. To do so, see which display area shows the flickering time.



- Open the Cover of the corresponding incubation area. The opening system lifts the cards so that they can be removed easily.
- Immediately remove the cards from the *DG Therm* incubator.

CAUTION!

Cards should be removed immediately after the end of incubation. After stopping the timer, the Thermal block does not modify the temperature and, therefore, cards continue being incubated if they are not removed.



6.2 Visualisation of Incubation Temperature

The *DG Therm* incubator allows momentarily seeing the incubation temperature. To do so, press **P1** or **P2** during the timing of an incubation batch.

The Display will show for a few seconds, in the part of the Display corresponding to the selected button, the temperature of the Thermal block at this moment.

After a few seconds, the Display again shows the time corresponding to this timing in progress.

NOTE:

Note that the temperature visualised when any of the two buttons **P1** or **P2** are pressed corresponds to the unique temperature of the entire Thermal blocks, in other words the same temperature for Incubation area **A** and **B**.




6.3 Timer Reset

Once the incubation batch has finished and its cards have been removed, press the corresponding button **P1** or **P2** again to leave the *DG Therm* incubator ready to carry out a new timing.

The *DG Therm* incubator will show in the part of the Display corresponding to this timer, the predefined incubation time.

6.4 Incubation Timing Stop

If, for any reason, it is necessary to stop the incubation timing before the established time is finished, **P1** or **P2** should be kept pressed down, for a few seconds. The *DG Therm* incubator will emit some intermittent acoustic signals that will end in a continuous signal to indicate the timing stop.

At this point, the Display will intermittently show the time indicated when the timer stopped and the indicator of Erroneous incubation time () will be activated.

CAUTION!



Incubation stop consists of stopping the timer but the temperature of the Thermal block is not modified and therefore, cards continue being incubated if they are not removed.

NOTE:



The *DG Therm* incubator has two independent timers **P1** and **P2**.

Stopping a timer does not imply interruption of the second timing in progress.

6.5 Modification of Pre-defined Timer Time

The *DG Therm* incubator has been programmed to carry out the incubation timing of those techniques with *DG Gel Cards* that require incubation at 37°C. Therefore, the pre-established incubation time is 15 minutes according to the corresponding Instructions for Use for the *DG Gel Cards*.

If for some reason timing for a period of time different from the predefined one has to be done, proceed as described below:

- Choose one of the timer 1 or 2 at rest (without working).
- Keep their corresponding button **P1** or **P2** pressed down until you hear a continuous acoustic signal and the timer flashes.
- Next, briefly press the same **P1** or **P2** button to modify the value of the established time value. Each push-button corresponds to 5 minutes and the maximum time permitted is 60 minutes.
- When the button is released, the *DG Therm* emits a continuous acoustic signal indicating that the predefined time has been modified and the following timing will take place during the time shown by the Display at this moment.

CAUTION!

When the incubation has finished with the timer modified by the OPERATOR, the *DG Therm* incubator will again show the time of 15 minutes predefined by Diagnostic Grifols, S.A.



6.6 Incubator Switch Off

To prolong the life of the *DG Therm* incubator, switch it off completely by means of the Mains switch (No.6, Figure 5) at the end of the working day.



7 MAINTENANCE

During the useful life under normal conditions indicated in section 3.1 “Technical Specifications”, maintenance of *DG Therm* is limited to regular cleaning and decontamination operations only. Once this period has passed, the equipment can still be used but, in addition to the regular cleaning and decontamination procedures, regular (at least yearly) temperature and functional inspections are recommended. These inspections can be performed by following the procedure given in section 8 “Operation Qualification (OQ) Procedure”.

7.1 Maintenance Plan

Maintenance plan is a set of operations carried out at regular intervals aimed at preserving function of the *DG Therm* incubator.

As a general rule and as long as there is no irregularity in the operation of the equipment, the maintenance plan that should be followed is the following:

PERIOD	ACTIVITY	CARRIED OUT BY
Whenever drops of samples or other substances spill on the Thermal block	Cleaning of the Thermal block and <i>DG Therm</i> Trays as indicated in section 7.1.1.	SUPERVISOR / OPERATOR
Each month	Decontamination of the equipment as indicated in section 7.1.2.	SUPERVISOR / OPERATOR

Decontamination operations carried out by the OPERATOR or any other interventions carried out by a QUALIFIED TECHNICIAN should be noted in the table, titled “Maintenance Services Log Sheet” included at the end of this User Manual.

Technical assistance may be provided by your supplier or other Technical Services authorised.

**WARNING!**

During cleaning and/or decontamination processes, protective gloves must be used by the OPERATOR.

**WARNING!**

Before the cleaning and decontamination procedures, all samples and cards should be removed from inside the equipment.

**WARNING!**

The cleaning processes of the equipment surfaces should be carried out with the equipment unplugged from the electric mains.

7.1.1 Cleaning Procedures

The *DG Therm* incubator has been manufactured with top-quality materials. However, biological samples, saline solutions, acidic or alkaline solvents should be eliminated from the exterior surface before these can cause deterioration.

Periodically clean the external surfaces with a damp cloth with a soft detergent.

The *DG Therm* Trays should also be cleaned (No.5, Figure 4). To do this, pull them outwards, remove them and clean with the same cloth. Once the cleaning has finished, return the Trays to their position.

**NOTE:**

If the *DG Therm* Trays are deteriorated, replace them.

WARNING!

For correct functioning of the card elevator system, it is necessary for the *DG Therm* Trays to be completely introduced into the incubator and correctly placed.

**WARNING!**

Take care of not leaking cleaning solution into the equipment openings.

**WARNING!**

Do not disassemble the equipment in any case. If there is liquid inside, the cleaning and decontamination operation should be carried out by a QUALIFIED TECHNICIAN. Call the nearest authorised Technical Service.



7.1.2 Decontamination of Equipment

DANGER!

Any part of the equipment that could come into contact with blood, serum samples or any other biological liquid should be treated as potentially contaminant.



In order to prevent any risk of infection, it is important to carry out decontamination of the instrument before performing certain operations.

Decontamination of the equipment should be carried out monthly or in the following cases:

- After spillages, leaks, etc. of potentially contaminant liquids.
- Preparation of the equipment for its transport or storage.

- Before Technical Service.
- Equipment disposal.

To decontaminate the equipment, proceed as indicated below:

- Switch off the equipment, disconnect it from the mains and wait until it reaches room temperature.
- In case of spillages, absorb the liquid with a disposable absorbent material (for example paper towels, gauze or paper clothes).
- Decontaminate the surface using a 0.5% (v/v) aqueous solution of sodium hypochlorite. To do this, clean the surfaces with disposable towels or cotton balls and dampen completely by dipping into the disinfectant solution.
- Absorb the disinfectant solution with a disposable material.
- Rinse the surface with a soft detergent with water to eliminate the odour and residual harmful chemical components.
- Dry the surface.
- Dispose of contaminated materials used during the decontamination in a container for biological waste.

WARNING!



Before using any cleaning or decontamination product different to those recommended by the manufacturer, the SUPERVISOR should verify with the manufacturer that the methods proposed will not damage the equipment.

NOTE:



The procedures described above do not guarantee that the equipment is totally decontaminated, but it reduces the risk of contamination to a minimum.

7.1.2.1 Decontamination Liquids

During handling of these liquids, the following recommendations should be followed:

- Corresponding Instructions for Use
- Laboratory safety regulations
- Local legislation in force on prevention

DANGER!

The sodium hypochlorite solution is corrosive, irritating for the skin and eyes and toxic if inhaled, absorbed or ingested.





8 OPERATION QUALIFICATION (OQ) PROCEDURE

The *DG Therm* incubator has two non-adjustable independent temperature sensors controlled by the incubator program itself. Given that the system of sensors has been calibrated by the manufacturer, if no function alarm is activated (see table in sections 12.1 and 12.2), it is warranted that the *DG Therm* will correctly work for all its useful life, without any additional calibration.

However, the procedure described below aims to provide a method for those laboratories which under a quality management system, must periodically verify that the *DG Therm* incubator meets its specifications. This procedure can also be applied a regular basis after the product useful life in case the equipment is not disposed.

The Operation Qualification (OQ) Procedure of the *DG Therm* incubator consists of verifying the correct function of the following parameters:

- Incubation temperature
- Incubation time
- Card elevator system

8.1 Required Materials

To qualify the operation of the *DG Therm* incubator the following materials are required:

- PT100 temperature probe for *DG Gel* Cards (Code. 230881)
- Digital thermometer for PT100 probes (Code. 230879)
- Calibrated chronometer (Precision: ± 1 s)
- 12 *DG Gel* Cards

To ensure the accuracy of temperature measurements, the temperature probe and the thermometer must be calibrated by using instruments controlled regularly with traceable materials at primary or secondary reference standards. The calibration certificate should be attached to both sets of equipment.

To maintain traceability, the probe and the thermometer have a label with the serial number, calibration certificate number, the calibration date and the validity period.

NOTE:

The use of a thermometer different from the one recommended is possible as long as it complies with the following specifications:



Thermometer: compatible for PT100
Temperature probes (PT385 100 Ohm)

Scale division (Resolution): $\leq 0,1^{\circ}\text{C}$


Minimum Range ($^{\circ}\text{C}$): 20 – 40 $^{\circ}\text{C}$

Maximum uncertainty permitted (thermometer
plus probe): $\pm 0.3^{\circ}\text{C}$ (at 37 $^{\circ}\text{C}$)

Connection: IEC

8.2 Temperature Qualification Procedure

To verify that the *DG Therm* incubator complies with the temperature specifications described in section 3.1 “Technical Specifications” proceed as described below:

- Verify that the *DG Therm* incubator is at room temperature and unplugged from the mains.
- Connect the Temperature probe for *DG Gel* Cards (code 230881) to the Thermometer.
- Insert the Temperature probe for cards in position 6 of Incubation area A of the Thermal block.
- Close the Cover ensuring that at least 30 cm of the cable of the probe is in contact with the Thermal block.
- Plug the *DG Therm* incubator to the mains and switch on the Main switch (No.6, Figure 5).
- Verify that the Display (No.4, Figure 4) is switched on and wait for the preheating phase to finish. The timer will indicate the predefined incubation time and the indicator of Temperature out of range () will be inactivated.
- Switch on the Thermometer.
- Wait for 15 minutes and verify that the thermometer temperature is within the temperature range defined in section 3.1 “Technical Specifications”.

- Furthermore, verify that the Display temperature, although do not be exactly the same than the thermometer temperature, is also within the temperature range defined in section 3.1 “Technical Specifications”.
- Switch off the Thermometer.
- Open the Cover of the *DG Therm* incubator and take out the Temperature probe.

NOTE:

Acceptance of the results enables ensuring correct function of the *DG Therm* incubator with respect to control of temperature.

Otherwise, verify that the Temperature probe for cards is correctly placed in the position of the incubator indicated in these Instructions for Use. If the results of the new verification are not accepted, contact your authorised Technical Service.



8.3 Procedure for Qualification of Time

To verify that the timers of the *DG Therm* incubator function correctly, proceed as described below:

- Ensure that timer 1 or 2 shows the predefined incubation time of 15 minutes.
- Press **P1** or **P2** and start the timer at the same time.
- Wait for the incubation time to finish and verify that the difference in measurement of time between the *DG Therm* incubator and the timer is less than 10 seconds.

NOTE:

Acceptance of the results enables ensuring correct function of the *DG Therm* incubator with respect to control of time.

Otherwise, repeat the test by ensuring synchronisation between the chronometer and the button. If after carrying out a new verification, results are not accepted, contact your authorised Technical Service.

8.4 Procedure for Qualification of Card Elevator System

To verify that the card elevator system of the *DG Therm* incubator functions correctly, proceed as described below:

- Verify that the *DG Therm* Trays of the incubator are completely introduced into their position and correctly positioned.
- Open the Cover of the incubator and place 12 *DG Gel* Cards into Incubation area A.
- Verify that all cards are kept elevated approximately 10 mm with respect to the Thermal block, facilitating the insertion and removal of the cards.
- Close the Cover of Incubation area A and verify that the *DG Gel* Cards are at the same level in the Thermal block.
- Open the Cover of incubation area A again and verify that all cards rise approximately 10 mm with respect to the Block.
- Remove the cards; close the Cover of Incubation area A.
- Repeat the procedure for Incubation area B.

NOTE:

If the cards do not rise sufficiently when the Cover of the incubator is opened or they are not totally at the same level when it is closed, verify that the *DG Therm* Trays are correctly positioned.

If the Trays are correctly positioned but the problem remains, contact your authorized Technical Service.

9 TRANSPORT AND STORAGE

WARNING!

The equipment must be decontaminated before being transported and/or stored.



If the *DG Therm* incubator has to be stored for a long period of time, it is recommendable to pack it as for transportation.

The required environmental storage conditions are those indicated in section 3.1 “Technical Specifications”.

The space requirements for storing the equipment are as follows:

- Size: 240 mm height x 400 mm depth x 400 mm width (with packaging).
- Approximate weight: 8 Kg

WARNING!

Only use the original packaging for transporting the equipment.





10 DISPOSAL OF THE EQUIPMENT

To dispose of the *DG Therm* incubator it should be completely cleaned and decontaminated and all remains of samples and reagents eliminated. Once this is done, it must be disposed as electronic waste, according to local, state and national regulation.

DANGER!

This instrument should only be disassembled by authorised specialists.

**CAUTION!**

When the instrument is at the end of its useful life, local legislation procedures in force should be followed to dispose it.





11 WARRANTY

The warranty conditions are established in separate documents. For more information, contact your distributor.

The warranty does not cover the following:

- Damages caused by its initiation and functioning in environments that contravene the Instructions for Use.
- Damages caused by accident, negligence or breach of the Instructions for Use.
- Damages caused for reasons of force majeure (atmospheric, geological phenomena, etc.).
- Damages caused by incorrect handling including that carried out by technical personnel not authorized.
- Parts of plastic or rubber as well as enamel and paints that have deteriorated due to knocks or usage except in the case of a manufacture defect.
- The *DG Therm* Trays.
- Breakdowns or defects due to transport.

The replacement of equipment or components will be subject to the criteria of Standard Conditions.

CAUTION!

Repairs should be exclusively carried out by qualified personnel authorised.









12 RESOLUTION OF INCIDENCES

During normal functioning of the *DG Therm* incubator certain warnings and incidences may appear that the OPERATOR can resolve without the assistance of the specialised Technical Service.

12.1 Warnings or Incidences


MESSAGE	DESCRIPTION	VERIFICATIONS
--:--	Incubator in preheating phase	<p>The symbols "--:--" indicate that the incubator is not yet ready to carry out an incubation batch because the Thermal block has not reached the work temperature yet.</p> <p>Once the work temperature has been reached, the luminous indicator of Temperature out of range will turn off and the timers will indicate the predefined incubation time</p>
	Temperature out of range	<p>The temperature sensors of the <i>DG Therm</i> incubator detect when the temperature of the Thermal block is outside established range. In this situation, the incubator cannot perform any timing. Verify that:</p> <ul style="list-style-type: none"> • The incubator is not in preheating phase (Display showing "--:--"). If after this phase, the temperature of the Thermal block is outside the established margins, the acoustic indicator will be activated with shorts sounds until a key is pressed.

MESSAGE	DESCRIPTION	VERIFICATIONS
		<ul style="list-style-type: none"> There has been no power cut that has stopped the work of the incubator. The timers will show by flashing, the value indicated at that moment and the incubator will emit shorts acoustics sounds. <p>After mains recovery, the incubator will go into preheating phase but will keep the Acoustic warning activated and will show the timer flashing.</p> <p>If the indicator  is displayed, switch off the incubator and switch it on again. If it is still displayed after the preheating phase, contact the authorised Technical Service.</p>
	Erroneous incubation time	<p>The timing of batch 1 or 2 was different to the pre-established time and the corresponding timer is flashing. This may be due to:</p> <ul style="list-style-type: none"> A timing stop by the OPERATOR as described in section 6.4. The timer shows by flashing, the value indicated at that moment. A power cut that has stopped the work of the incubator. The timer will show by flashing, the value indicated at that moment and will activate the Acoustic alarm. <p>Press the button corresponding to this timer to stop the Acoustic alarm, so the timer is prepared for a new incubation batch.</p>

MESSAGE	DESCRIPTION	VERIFICATIONS
	Contact the authorised Technical Service	<p>If the incubator detects any imbalance in its function that cannot be resolved by the OPERATOR, the corresponding indicator is activated.</p> <p>In this case, switch off the incubator and restart again. If the warning persists contact the authorised Technical Service.</p>

12.2 Error Messages

When an error occurs in any element of the system, the equipment will carry out the following actions:

- Stop temperature regulation.
- Ignore Buttons **P1** and **P2**.
- Activate the Acoustic alarm with short sounds.
- Activate the indicator .
- Show an **E** on the Display with the corresponding error code.

CAUTION!

If the *DG Therm* incubator shows an error code in the Display, restart the equipment. If the error persists, contact the authorised Technical Service and indicate the error code.



12.3 Acoustic Alarm

The *DG Therm* incubator has an Acoustic alarm that can be programmed at three levels, and when configured, it can be activated with the volume selected by the OPERATOR in the following situations:

- When the correct incubation temperature is reached. A short sound indicates that the preheating phase has finished, the luminous indicator of Temperature out of range is inactivated and timers indicate the predefined incubation time.
- Once the timing of the incubation batch has been completed. The Acoustic indicator will be activated with a continuous sound.
- When timing is stopped by keeping the corresponding button pressed down. The *DG Therm* incubator emits three short sounds and a continuous one indicating that timing has stopped at this time.
- After a power cut during the timing of an incubation batch. When it works again, the *DG Therm* incubator will emit a continuous sound and the timer will show by flashing the value indicated at the stop time.
- After the preheating phase, if the temperature of the Thermal block is outside established range. The *DG Therm* incubator emits a continuous sound and the indicator Temperature out of range is displayed.
- In general, as long as the incubator detects an error situation (see section 12.2), it will emit a continuous sound.

**CAUTION!**

To stop the Acoustic alarm, press **P1** or **P2** as appropriate. If the Acoustic alarm continues, contact the authorised Technical Service.

MAINTENANCE SERVICES LOG SHEET

Model:	Serial No:	Installation date:	
DATE	ACTION CARRIED OUT	PERFORMED BY	SUPERVISED BY